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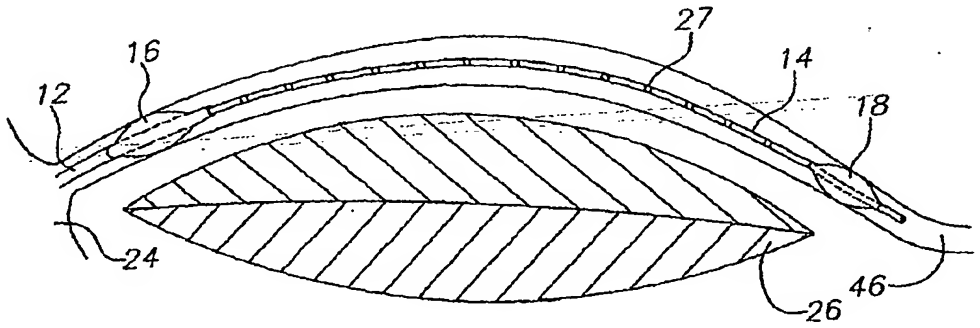


(57) Abstract: A diagnostic device for determining the amount of change required in a coronary sinus to reduce valve regurgitation. The device includes a distal tube (14) having a distal anchor (18) at a distal end portion of the distal tube, a proximal tube (12) having a proximal anchor (16) at a distal end portion of the proximal tube, and an adjustor to move the distal tube relative to the proximal tube. The proximal tube and the distal tube together form a telescoping elongate body adapted to fit within the coronary sinus, and the device includes a scale (27) to measure the movement of the distal anchor relative to the proximal anchor.

WO 2006/063108 A1

30

DIAGNOSTIC KIT TO ASSIST WITH HEART VALVE ANNULUS ADJUSTMENT

This invention relates to apparatus and methods for heart valve repair and, more particularly, to a diagnostic kit to assist with heart valve annulus adjustment for improving heart valve function using devices inserted into vessels surrounding the target valve.

BACKGROUND

Heart valve regurgitation, or leakage from the outflow to the inflow side of a heart valve, is a common occurrence in patients with heart failure and a source of morbidity and mortality in these patients. Usually regurgitation will occur in the mitral valve, located between the left atrium and left ventricle, or in the tricuspid valve, located between the right atrium and right ventricle. Mitral regurgitation in patients with heart failure is caused by changes in the geometric configurations of the left ventricle, papillary muscles and mitral annulus. Similarly, tricuspid regurgitation is caused by changes in the geometric configurations of the right ventricle, papillary muscles and tricuspid annulus. These geometric alterations result in mitral and tricuspid leaflet tethering and incomplete coaptation in systole.

Heart valve repair is the procedure of choice to correct heart regurgitation of all etiologies. With the use of current surgical techniques, between 40% and 60% of regurgitant heart valves can be repaired, depending on the surgeon's experience and the anatomic conditions. The advantages of heart valve repair over heart valve replacement are well documented. These advantages include better preservation of cardiac function and reduced risk of anticoagulant-related hemorrhage, thromboembolism and endocarditis.

Recently, several developments in minimally invasive techniques for repairing heart valves without surgery have been introduced. Some of these techniques involve introducing systems for remodeling the mitral annulus through the coronary sinus.

The coronary sinus is a blood vessel commencing at the coronary ostium in the right atrium and passing through the atrioventricular groove in close proximity to the posterior, lateral and medial aspects of the mitral annulus. Because of its position adjacent to the mitral annulus, the coronary sinus provides an ideal conduit for positioning an endovascular prosthesis to act on the mitral annulus and thereby reshape it.

Examples of minimally invasive apparatus for heart valve repair can be found in U.S. Patent No. 6,210,432 to Solem, et al., U.S. Ser. No. 09/775,677 to Solem, et. al. filed on February 5, 2001, U.S. Ser. No. 10/303,765 to Solem, et. al. filed on November 26, 2002, U.S. Ser. No. 10/141,348 to Solem, et. al. filed on May 9, 2002, U.S. Ser. No. 10/329,720 to Solem, et. al. filed on December 24, 2002, U.S. Ser. No. 10/714,462 to Solem, et. al. filed on November 13, 2003 and U.S. Ser. No. 60/530352 to Solem, et al. filed on December 16, 2003 (the '352 application) all of which are incorporated herein by reference.

One specific example of a minimally invasive apparatus for heart valve repair, as described in greater detail in the '352 application, and as shown in FIGs. 10 and 11 herein, includes an elongate body 410 having a proximal anchor 412 and a distal anchor 414 connected by a bridge 416. The proximal and distal anchors 412, 414 are both stents made from nitinol and both anchors have a mesh configuration including loops 54 of zigzag shaped material having alternating peaks 42. The loops 54 are connected at each peak 42 to form rings 56 of four-sided openings. Both the proximal anchor 412 and the distal anchor 414 are

transferable between a compressed state, in which the anchors have a diameter that is less than the diameter of the coronary sinus, and an expanded state, in which the anchors have a diameter that is about equal to or greater than the diameter of the coronary sinus.

As shown in FIG. 10, the bridge 416 is connected between the proximal anchor 412 and the distal anchor 414 by links 418, 419. As shown in more detail in FIG. 11, the link 419 has a base 421 and arms 422 that extend from the base and which are connected to the anchor 414. The link also includes a hole 428 which serves as a means through which resorbable thread 420 may be secured to the bridge.

The bridge 416 is made from a shape memory material and is flexible to allow the body 410 to conform to the shape of the coronary sinus. The bridge 416 includes connected X-shaped elements 424 having a space 425 between adjacent elements. The bridge has two states, an activated state in which the bridge 416 has a first length and a non-activated state, in which the bridge has a second length, the second length being longer than the first length. Resorbable thread 420 which acts as a temporary spacer is woven into the spaces 425 to hold the bridge in its longer non-activated state.

The body is inserted into the coronary sinus of a patient with both anchors 412, 414, in the compressed state and the bridge 416 including resorbable thread 420 in the longer non-activated state. After the anchors 412, 414 are placed in a desired location, they are transformed into their expanded state in which they serve to attach the body 410 to the coronary sinus. After a period of time, during which the wall of the coronary sinus grows around the anchors 412, 414, the resorbable thread dissolves and the bridge 416 transforms from its longer non-activated state to its shorter activated state. The shortening of the bridge

416 draws the proximal anchor 412 and the distal anchor 414 closer together, cinching the coronary sinus and reducing its circumference. This reduction of the circumference of the coronary sinus closes the gap causing mitral regurgitation.

Valve annulus reshaping devices, including those described above, may be manufactured such that they can vary in certain dimensions or characteristics. For instance, the devices may be manufactured so that they foreshorten or otherwise change shape by a specific amount depending on how much reshaping of a valve is necessary. In other words, a physician may have a choice between using a reshaping device that severely remodels an annulus, one that only slightly remodels an annulus, or one that is custom designed to remodel an annulus by a specific amount. Additionally, the valve reshaping devices may also be manufactured to have different lengths and/or anchor sizes. Due to varying degrees of the severity of mitral and tricuspid valve leaflet coaptation as well as varying sizes and lengths of heart valve annuli, it would be advantageous for a physician to know how much reshaping of the valve annulus is necessary as well as having an idea of the size and length of the annulus before inserting the valve reshaping device. This knowledge would allow the physician to choose a device that could reshape the valve annulus by an appropriate amount. Thus, there is a need for a device that a physician may use to gauge the amount of reshaping necessary in a heart valve annulus and/or the size and length of the annulus. Such a device would allow the physician to select an annulus reshaping device to insert into a patient that more closely approximates the amount of reshaping necessary for that specific patient as well as a device that may be custom designed to fit the size and length of the patient's annulus.

SUMMARY

A diagnostic device for determining the amount of change desired in a cardiac vessel to reduce valve regurgitation is disclosed. The diagnostic device comprises a distal tube (or other suitable elongate body) having a distal anchor attached at a distal end of the distal tube, a proximal tube (or other suitable elongate body) having a proximal anchor attached at a distal end of the proximal tube, and an adjustor by which the distal tube may be moved relative to the proximal tube. In one embodiment, the device may be inserted into the coronary sinus. The proximal tube and the distal tube together form a telescoping elongate body adapted to fit within the coronary sinus. Additionally, the distal tube includes a plurality of radiopaque markers spaced evenly thereon to provide a means for measuring the distance moved by the distal tube relative to the proximal tube, the distal anchor and the proximal anchor are transformable between a compressed state and an expanded state, and movement of the adjustor by a specified distance causes movement of the distal tube by the same distance. The proximal and distal anchors may be balloons, baskets or stents.

A method for determining the amount of change to the coronary sinus necessary to reduce mitral regurgitation is also disclosed. Such method includes inserting a diagnostic device into the coronary sinus, anchoring a distal anchor to the coronary sinus, anchoring a proximal anchor to the coronary sinus, using an adjustor to move the distal anchor proximally such that mitral regurgitation is reduced and measuring the proximal movement of the distal anchor and simultaneously measuring the amount of mitral valve regurgitation.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a three-dimensional view of the mitral valve and coronary sinus.

FIG. 2 is a side view of one exemplary embodiment of a diagnostic device of the present invention including a proximal tube with a proximal anchor and a distal tube with a distal anchor in a compressed state.

FIG. 3 is a side view of embodiment of FIG. 2 including a proximal anchor and a distal anchor in an expanded state.

FIG. 4a is a cross-sectional view of a telescoped proximal tube and distal tube of the current invention.

FIG. 4b is a cross-sectional view of a distal tube of the current invention.

FIG. 5 is a cross-sectional view of a coaxial proximal tube and distal tube of the current invention.

FIG. 6 is a perspective view of an alternate anchor according to the present invention.

FIG. 7 is a side view of the diagnostic device of FIG. 2 after the device has been initially inserted into the coronary sinus and before expansion of the distal anchor.

FIG. 8 is a side view of the diagnostic device of FIG. 2 positioned for use in the coronary sinus with the distal anchor and the proximal anchor in the expanded state.

FIG. 9 is a side view of the diagnostic device of FIG. 2 after the device has been used to reduce an anterior-posterior distance between leaflets of a mitral valve.

FIG. 10 is an exemplary embodiment of a recent mitral valve repair device.

FIG. 11 is a detail of the mitral valve repair device of FIG. 10.

DETAILED DESCRIPTION

Although the devices and methods described below may be used in any appropriate heart valve annulus, for ease and consistency of explanation the devices and methods below will be described with specific reference to the mitral valve and mitral annulus.

Referring to **FIG. 1**, a coronary sinus **20** extends from a right atrium **22** and a coronary ostium **24** and wraps around a mitral valve **26**. The term coronary sinus is used herein as a generic term to describe a portion of the vena return system that is situated adjacent to the mitral valve **26** along the atrioventricular groove. The term coronary sinus **20** used herein generally includes the coronary sinus, the great cardiac vein and the anterior interventricular vein. A mitral annulus **28** is a portion of tissue surrounding a mitral valve orifice to which several leaflets attach. The mitral valve **26** has two leaflets, an anterior leaflet **29** and a posterior leaflet **31.** The posterior leaflet has three scallops **P1, P2** and **P3** which, in a healthy mitral valve coapt with the anterior leaflet **29** to prevent regurgitation of blood through the valve.

The problem of mitral regurgitation often results when a posterior aspect of the mitral annulus **28** dilates and displaces one or more of the posterior leaflet scallops **P1, P2** or **P3** away from the anterior leaflet **29** causing a gap to be formed through which regurgitation occurs. To reduce or eliminate mitral regurgitation, therefore, it is desirable to move the posterior aspect of the mitral annulus **28** in an anterior direction and close the gap caused by the leaflet displacement.

As shown in **FIGs. 2 and 3**, an embodiment of the diagnostic device **10** of the present invention comprises a proximal tube **12** and a distal tube **14**. The diagnostic device **10** may be of dimensions such that it is insertable into a vessel

adjacent a heart valve such as the coronary sinus and the anterior right ventricular cardiac vein. Additionally, the diagnostic device **10** may be flexible enough to allow it to adapt to the curvature of the vessel into which it is inserted.

As shown in **FIG. 4a**, the proximal tube **12** may be a plastic tube having two lumens, a tube lumen **35** and an inflation lumen **37**. The tube lumen **35** allows the distal tube **14** to pass through the proximal tube **12**. The inflation lumen serves as a channel through or by which an inflation gas or liquid may expand an anchor, as is also described in greater detail below. This tube configuration may be used when the anchor is inflatable, such as a balloon. In one preferred construction, the proximal tube is formed of nylon tubing having an outer diameter of about 0.130 inches. The tube lumen **35** preferably has a diameter of about 0.085 inches. In one alternative embodiment, the inflation lumen in the proximal tube may be formed with a crescent or oval shape. In another alternative embodiment, the proximal tube may be formed with two or more inflation lumens to increase the cross-sectional flow area. In yet another alternative embodiment, the proximal portion of the proximal tube may be fitted with a plastic strain relief tubing and a hub for communicating with the tube lumen and inflation lumen.

As shown in **FIG. 4b**, the distal tube may also contain two lumens, a guidewire lumen **19** and an inflation lumen **21**. The guidewire lumen **19** serves as a channel on which the distal tube **14** may travel as it is inserted into a patient as is described in greater detail below. In one preferred embodiment, the guidewire lumen **19** is formed with a diameter of about 0.042 inches. The inflation lumen **21** serves as a channel through or by which an inflation gas or liquid may expand an anchor, as is also described in greater detail below. This tube configuration may be used when the anchor is inflatable, such as a balloon.

In one preferred construction, the distal tube is formed of Pebax 55D tubing having an outer diameter of about 0.067 inches. The guidewire lumen **19** preferably has a diameter of about 0.042 inches. In one alternative embodiment, the inflation lumen in the distal tube may be formed with a crescent or oval shape. In another alternative embodiment, the distal tube may be formed with two or more inflation lumens to increase the cross-sectional flow area through the tube. In yet another alternative embodiment, the proximal portion of the distal tube is surrounded by a stainless steel braided polyamide tubing having an inner diameter of about 0.0725 inches and an outer diameter of about 0.0780 inches to stiffen the proximal portion and enhance pushability. The proximal portion may also be fitted with a hub for communication with the guidewire and inflation lumens.

FIG. 5 shows an alternate configuration wherein the distal tube **14** includes an inner tube **68** and an outer tube **66** that are coaxial. Based on this configuration, a guidewire lumen **64** is formed inside the inner tube **68** and an expansion lumen **62** is formed between the inner tube and the outer tube **66**. This tube configuration may be used when the anchor is inflatable, such as a balloon, or mechanically expandable, such as a basket. This coaxial tube configuration may also be used for the proximal tube **12**. It will also be appreciated that in some configurations the proximal tube **12** passes through the distal tube, rather than vice versa, as described above.

The distal tube **14** may further include radiopaque marker bands **27** spaced along the outer perimeter of the tube as shown in **FIG. 2**. The marker bands **27**, which are visible under fluoroscopy, serve to indicate the position of the distal tube **14** when the tube is positioned within a vessel. Additionally, the marker bands **27** may be used to measure a desired portion of the coronary sinus and the amount of movement by the distal tube **14** as is described in greater detail

below. The marker bands **27** may be platinum bands or any other biocompatible band visible under fluoroscopy or other suitable visual means. The specific number of bands **27** included along the distal tube **14** is not critical, but preferably there are a sufficient number of bands to allow the entire exposed length of the tube in the coronary sinus to be visible under fluoroscopy. In one preferred embodiment, the distal tube comprises marker bands disposed along about 14 cm of the distal end portion. The marker bands are preferably spaced apart by about 1 cm. Further, there are a sufficient number of bands **27** to allow the bands to act as distance markers for movement of the distal tube **14**. A similar number of markers are located on the distal tube outside of the patient visible for the human eye. These markers are visible and may be counted even without the help of fluoroscopy.

The distal tube **14** also includes a distal anchor **18** located at or near the distal end of the distal tube. In one embodiment, the distal anchor **18** has two states, a compressed state and an expanded state. In the compressed state, the distal anchor **18** is insertable into the coronary sinus **20** or other coronary vessel. In the expanded state, the distal anchor **18** secures the distal tube **14** to an inner wall of the vessel into which it has been inserted. The distal anchor **18** is transformable from the compressed state to the expanded state by a transformation means. Such transformation means may be mechanical, electrical or chemical. Additionally, the distal anchor **18** may be self-expanding.

As shown in **FIGs. 2 and 3** in one exemplary embodiment, the distal anchor **18** is a compliant balloon which conforms to the size and shape of the vessel into which it is expanded. The balloon may be attached to the distal or proximal tube by a thermal or adhesion bond, or by any other appropriate attachment means. The balloon may be manufactured such that it has a safety mechanism

that will reduce the possibility of the balloon damaging a vessel into which it is inserted. For instance, the balloon may be designed to have a maximum pressure to which it can be inflated. Additionally, the balloon may be designed with a "slow leak" which gradually reduces its internal pressure. Since the compliant balloon will conform to the size of the vessel and because the balloon is visible under fluoroscopy, an observer will be able determine the size of the vessel at the balloon location by viewing the balloon on a screen having dimension markers. Knowing the approximate size of the vessel into which a valve repair device will be inserted may allow for a more accurate decision to be made as to which particular valve repair device should be selected from an array of devices to use on a patient. In one preferred configuration, the distal anchor **18** is a compliant balloon formed of Pebax 55D and having a length of about 20 mm. The compliant balloon preferably has inflated diameters ranging from about 4 mm at 1 atmosphere to about 9 mm at 8 atmospheres. In alternative configurations, the balloon may be formed of any other suitable material, such as, for example, nylon, polyurethane and polyethylene. In one embodiment, the distal tubing is further provided with an atraumatic distal tip. The distal tip is preferably made of Pebax 40D. In other alternate embodiments of the diagnostic device **10**, the distal anchor **18** may be a basket, a stent, or any other expandable device adapted to secure the device inside a vessel.

The balloon may be transformed from its compressed state to its expanded state by using a biocompatible fluid, and more specifically, a saline solution. The fluid may be introduced through a catheter (not shown) and may be transported through the inflation lumen **21, 62 (FIGs. 4 and 5)** to the balloon.

In an alternate embodiment as shown in **FIG. 6**, a basket **30** may be used as a distal anchor. In one embodiment, the basket **30** has two states, a compressed state and an expanded state. In the compressed state, the basket **30** is insertable

into the coronary sinus or other coronary vessel. More specifically, in the compressed state the basket **30** may be substantially cylindrical and may include a plurality of strands **32** extending longitudinally from a proximal end **34** to a distal end **36** of the basket spaced evenly around the basket's circumference. The distal end **36** of the basket **30** may be adapted to be fitted onto an inner tube **68** and the proximal end **34** of the basket may be adapted to be fitted onto an outer tube **66** (see **FIG. 5**). In one embodiment, the outer tube **66** may also be the distal tube **14**. When the inner tube **68** and the outer tube **66** are moved relative to each other, the basket **30** may be expanded or contracted. In the expanded state, the basket **30** is secured to an inner wall of the vessel into which it has been inserted. In the expanded state, wherein the distance between the proximal end **34** and the distal end **36** of the basket **30** is decreased, the strands **32** may become triangularly-shaped with the apex of the triangle protruding away from the center of the basket. In one exemplary embodiment, the strands **32** may be made from a shape memory material (e.g. nitinol) allowing the basket **30** to transform from its compressed state to its expanded state by, for example, retraction of a sheath (not shown) covering the basket.

Similarly to the distal tube **14**, the proximal tube **12** may have a proximal anchor **16** located at or near the distal end of the proximal tube. Like the distal anchor **18**, the proximal anchor **16** may have a compressed state for delivery into a vessel and an expanded state for anchoring the distal tube to the vessel. The proximal tube **12** may further include an inflation lumen **37** for transforming the proximal anchor **16** between the compressed state and the expanded state. In one preferred configuration, the proximal anchor 16 is a balloon having a length of about 30 mm and formed of polyurethane. In alternative configurations, the balloon may be formed of any other suitable material, such as, for example, nylon, Pebax and polyethylene.

The distal tube **14** and the proximal tube **12** of the diagnostic device **10** may be slidably connected to each other in a telescoping manner to form an elongate body. In one exemplary embodiment, the outer diameter of the proximal tube **12** is greater than the outer diameter of the distal tube **14**, allowing the distal tube to fit within the proximal tube. The movement of the distal tube **14** may be controlled by using a handle (not shown). More specifically, the distal tube **14** may be attached to a collar which is slidable along the handle. When the collar is moved proximally, the distal tube **14** is also moved proximally by the same distance. Similarly, when the collar is moved distally, the distal tube **14** is moved distally by the same distance. In one exemplary embodiment, the body of the handle may include distance markers which allow the movement of the collar, and thus the movement of the distal tube **14**, to be measured.

In one exemplary embodiment, the diagnostic device **10** may be deployed as follows. First, a guidewire **(not shown)** is inserted into the coronary sinus past the great cardiac vein and deep into the arterioventricular vein. The diagnostic device **10** may be mounted coaxially on a delivery catheter (not shown), and inserted into the coronary sinus **20** over the guidewire. Proximal ends of the distal tube **14** and proximal tube **12** may extend out of the patient's body where they are attached to a handle. Additionally, the proximal anchor **16** and the distal anchor **18** are adjacent as the diagnostic device **10** is inserted into the coronary sinus **20**.

When initially inserted into a patient, the diagnostic device **10** is inserted into the coronary sinus **20** as distally as possible. Specifically, the diagnostic device **10** may be inserted into the part of the coronary sinus known as the great cardiac vein **46** as shown in **FIG. 7**. Because of its naturally curved shape and higher concentration of fatty tissue, the great cardiac vein **46** allows for high

resistance to movement and provides a natural anchoring location for the distal anchor **18**.

Once the distal tube **14**, and more specifically, the distal anchor **18** have been placed in the desired position in the coronary sinus **20**, the distal anchor may be transformed from its compressed state into its expanded state. In one embodiment, where the distal anchor **18** is a balloon, a biocompatible fluid will be introduced into the inflation lumen **37** to inflate the balloon. In an alternate embodiment, where the distal anchor **18** is a mechanically expandable anchor, such as a basket **30** (**FIG. 6**), manipulation of the inner tube **68** and the outer tube **66** (**FIG. 5**) will cause the anchor to transform into its expanded state. In yet another embodiment, where the anchor is self-expandable, a delivery sheath is used to cover the anchors and retraction of the delivery sheath will cause the anchor to transform into its expanded state.

Once the distal anchor **18** has been expanded such that the anchor is in contact with the inner walls of the coronary sinus **20**, the proximal tube **12** is pulled proximally using the handle. The distance markers on the handle as well as the radiopaque markers **27** on the distal tube **14** allow the distance that the proximal tube **12** has moved to be measured. The proximal tube **12** is pulled proximally until the proximal anchor **16** is adjacent the ostium **24** of the coronary sinus **20**. Alternatively, the proximal anchor may be placed in the right atrium outside of the coronary sinus ostium **24**, abutting the ostium, but not blocking the ostium. Radiopaque markers **27** on the distal tube **14** are visible on a monitoring screen and aid a user in locating the proximal anchor **16** in the coronary sinus **20**. After the proximal anchor **16** is placed in its desired location, the proximal anchor is transformed from its compressed state into its expanded state (**FIG. 8**). As described above, in an embodiment wherein the proximal anchor **16** is a balloon, a biocompatible fluid will be introduced into the inflation lumen **21** to

inflate the balloon In the embodiment wherein the proximal anchor **16** is a self-expanding anchor, such as a basket **30** (**FIG. 6**), the retraction of the delivery sheath proximal to the proximal anchor will cause the anchor to transform into its expanded state.

Once both the proximal anchor **16** and the distal anchor **18** have been transformed from their compressed state into their expanded state, the handle may be used to pull the distal tube **14** proximally. Pulling the distal tube **14** proximally will have at least one of two effects on the coronary sinus **20**. The first effect may be to cinch the coronary sinus **20** tighter around the mitral valve **26**, decreasing the distance between the anterior leaflet **29** and posterior leaflets **31**. The second effect may be to decrease the radius of curvature of the coronary sinus **20**, which may also decrease the distance between the anterior leaflet **29** and posterior leaflets **31**. This change in the shape of the mitral valve **26** allows the gap caused by mitral regurgitation between the anterior leaflet **29** and the posterior leaflet **31** to close (**FIG. 9**), thus decreasing or eliminating mitral regurgitation.

As the radius of curvature of the coronary sinus is decreased and the gap between the anterior leaflet **29** and posterior leaflet **31** of the mitral valve is reduced, the amount of regurgitation is measured. This measurement is preferably performed by ultrasound with the ultrasound probe located on the chest, in the esophagus or inside the heart of the patient. When the regurgitation is at a minimum, and particularly when there is no regurgitation, the distance the distal tube **14** has moved relative to the proximal tube is noted, for instance, by using the radiopaque markers as a measuring tool.

Once mitral regurgitation has been eliminated or reduced by the desired amount, and the distance the distal tube **14** must be moved to achieve the desired effect

has been measured, the distal anchor **18** and the proximal anchor **16** are transformed back from their expanded state to their compressed state. In the embodiment where the anchors **16, 18** are balloons, the fluid used to inflate the balloons is removed. In the embodiment where the anchors **16, 18** are self-expanding, the delivery sheath is reinserted over each anchor. In the embodiment where the anchors **16, 18** are baskets **30**, the inner tube **68** and the outer tube **66** are moved apart from one another to transform the anchor into its compressed state.

After the proximal anchor **16** and the distal anchor **18** have been returned to their compressed state, the proximal tube **12** and the distal tube **14** are retracted proximally along the guidewire from the coronary sinus **20** and out of the patient's body. Once the diagnostic device **10** has been removed, a valve repair device may be inserted along the guidewire to more permanently repair the mitral valve regurgitation. Based on information about the coronary sinus **20** received from the diagnostic device **10**, such as the length of the coronary sinus, and information about the amount of foreshortening necessary to achieve the desired reduction of mitral regurgitation, an appropriate valve repair device may be selected from an array of such devices having various (or variable) diameters and/or foreshortening lengths.

While the foregoing described the preferred embodiments of the invention, it will be obvious to one skilled in the art that various alternatives, modifications and equivalents may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A diagnostic device for determining an amount of adjustment required in a coronary sinus to reduce heart valve regurgitation comprising:

a first elongate body having a distal anchor at a distal end portion of the first elongate body,

a second elongate body having a proximal anchor at a distal end portion of the second elongate body, and

an adjustor to move one of the first and second elongate body relative to the other of the first and second elongate bodies,

wherein the first and second elongate bodies together form a telescoping elongate body adapted to fit within the coronary sinus, and

further comprising a scale to permit measurement of the movement of the distal anchor relative to the proximal anchor.

2. The diagnostic device of claim 1, wherein the scale is on the elongate body.

3. The diagnostic device of claim 2, wherein the scale is a plurality of markers.

4. The diagnostic device of claim 3, wherein the markers are spaced evenly along the elongate body.

5. The diagnostic device of claim 1, wherein the scale is on the adjustor.

6. The diagnostic device of claim 1, wherein the distal anchor and the proximal anchor are transformable between a compressed state and an expanded state.

7. The diagnostic device of claim 1, wherein movement of the adjustor by a certain distance causes movement of the distal tube by the same distance.

8. The diagnostic device of claim 1, wherein the distal anchor and the proximal anchor are balloons.

9. The diagnostic device of claim 8, wherein the distal anchor and the proximal anchors are transformed from their compressed state to their expanded state by a fluid.

10. The diagnostic device of claim 1, wherein the distal anchor is a basket.

11. The diagnostic device of claim 1, wherein each of the first and second elongated bodies contain an inflation lumen and a guidewire lumen.

12. The diagnostic device of claim 1, wherein the adjustor is a handle.

13. A method for determining an amount of adjustment to a coronary

sinus necessary to reduce heart valve regurgitation comprising:

inserting a diagnostic device into a coronary vessel adjacent to the cardiac valve, the diagnostic device including a distal anchor and a proximal anchor,

anchoring the distal anchor to the coronary sinus,

anchoring the proximal anchor to the coronary sinus,

adjusting at least one of the distal and proximal anchors to reduce heart valve regurgitation, and

measuring the adjustment.

14. The method of claim 13, wherein anchoring the proximal and distal anchors comprises expanding the anchors from a compressed state to an expanded state.

15. The method of claim 13, wherein expanding the distal anchor and the proximal anchor comprises expanding by a fluid.

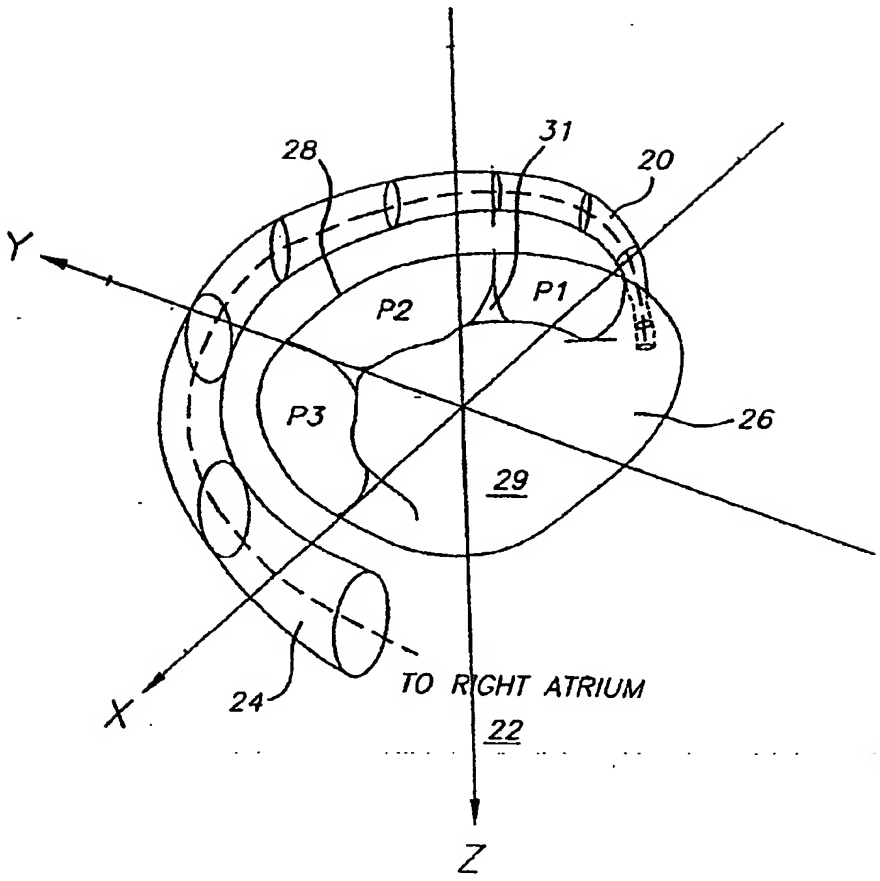
16. The method of claim 13, wherein inserting the diagnostic device comprises inserting the diagnostic device into a great cardiac vein portion of the coronary sinus.

17. The method of claim 13, wherein adjusting comprises straightening the curvature of the coronary sinus.

18. The method of claim 13 wherein adjusting comprises cinching the coronary sinus.

19. The method of claim 13 further comprising selecting a therapy device and securing the therapy device to the coronary sinus.

FIG. 1



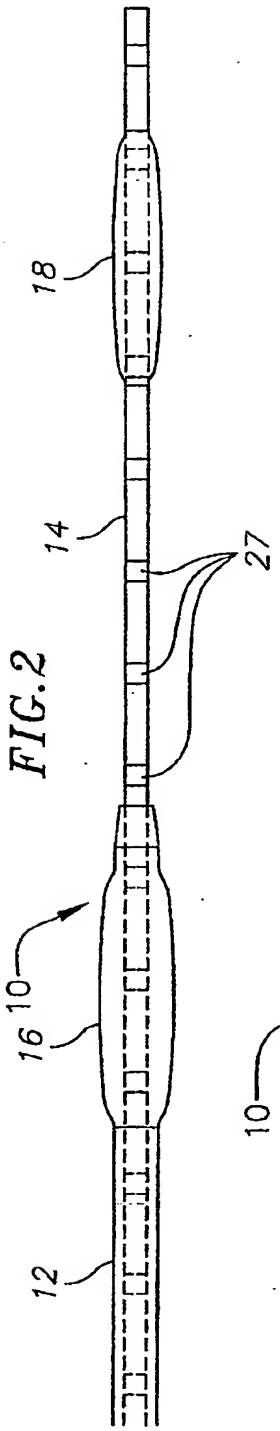


FIG.2

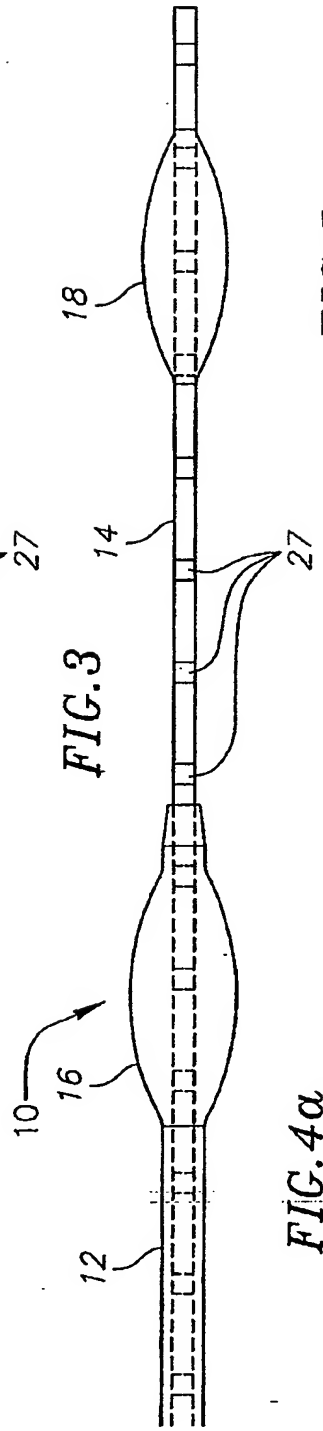


FIG.3

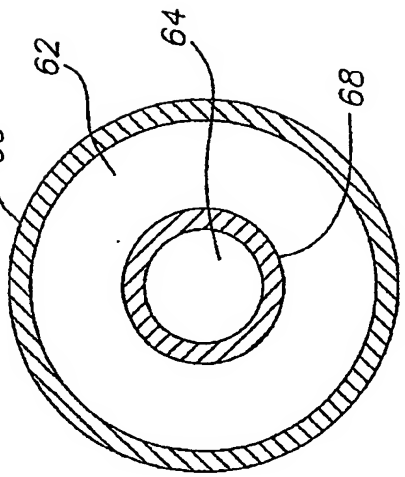


FIG.5

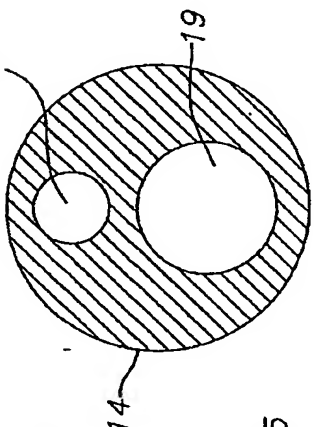


FIG.4b

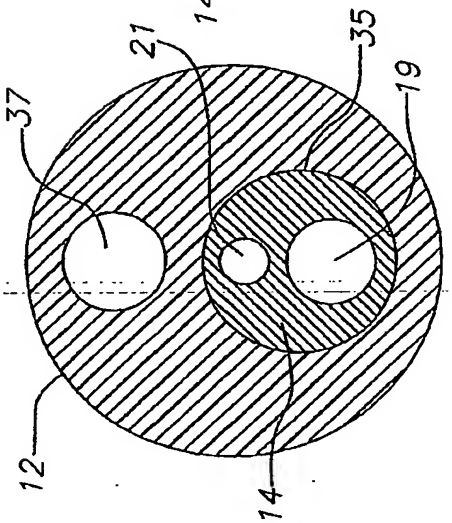


FIG.4a

FIG. 6

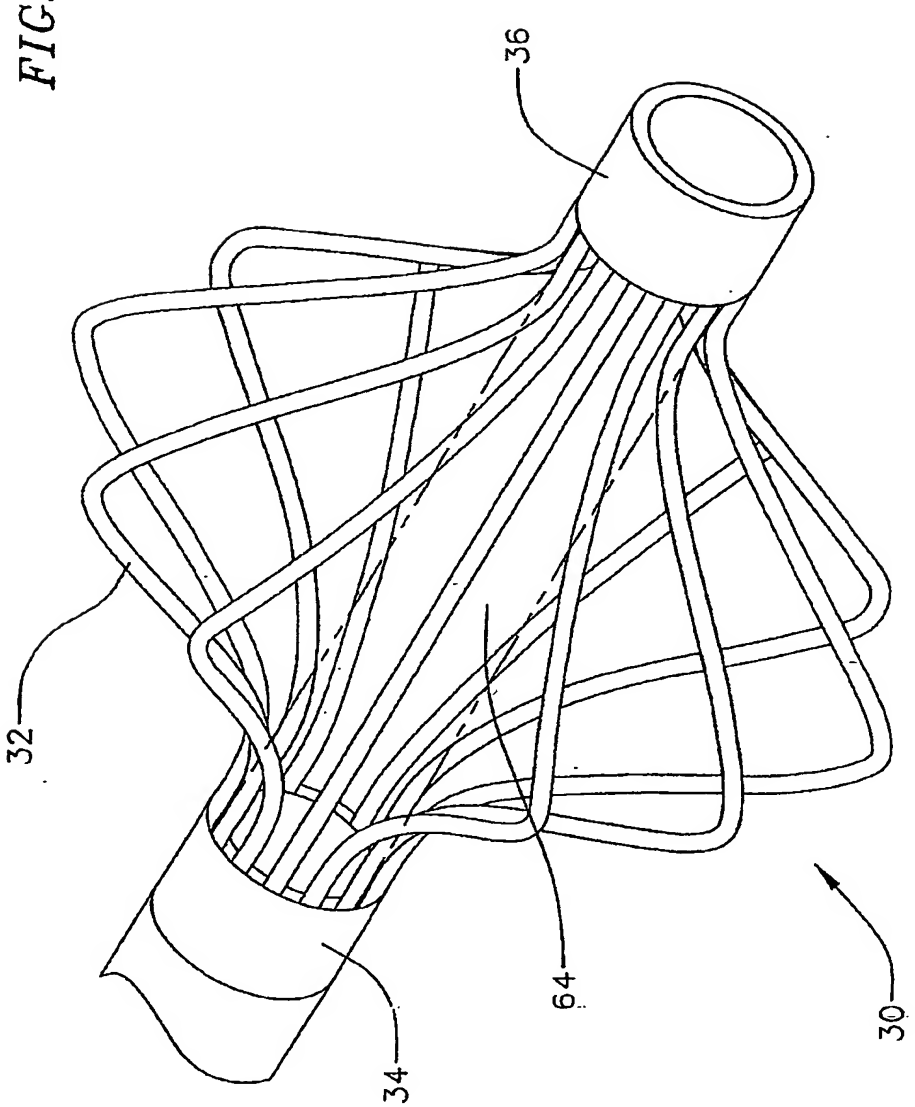


FIG. 7

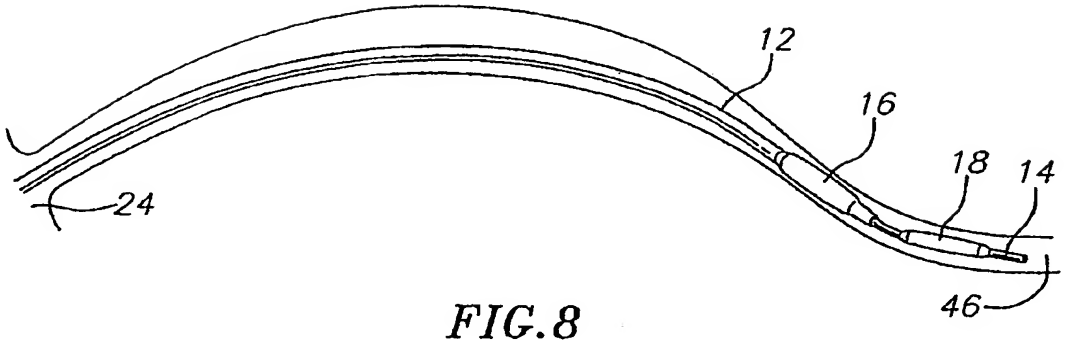


FIG. 8

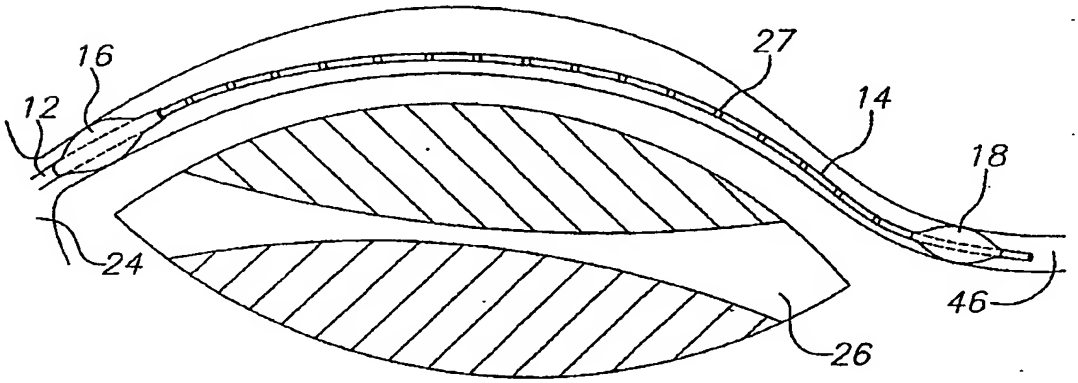
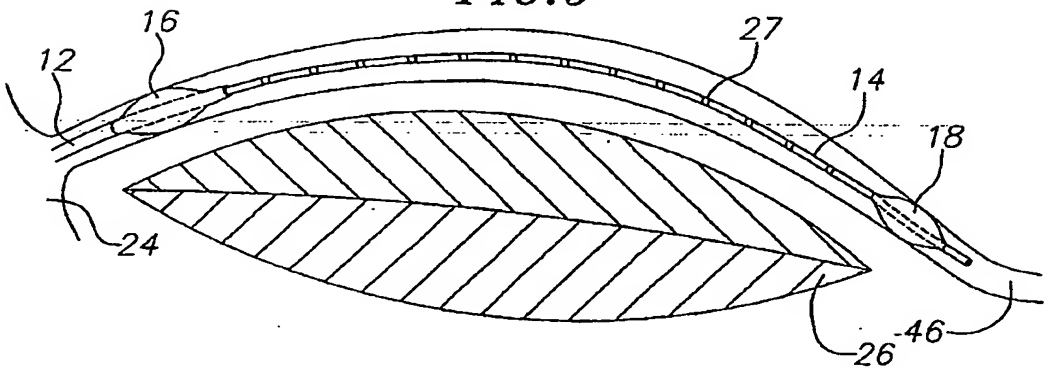


FIG. 9



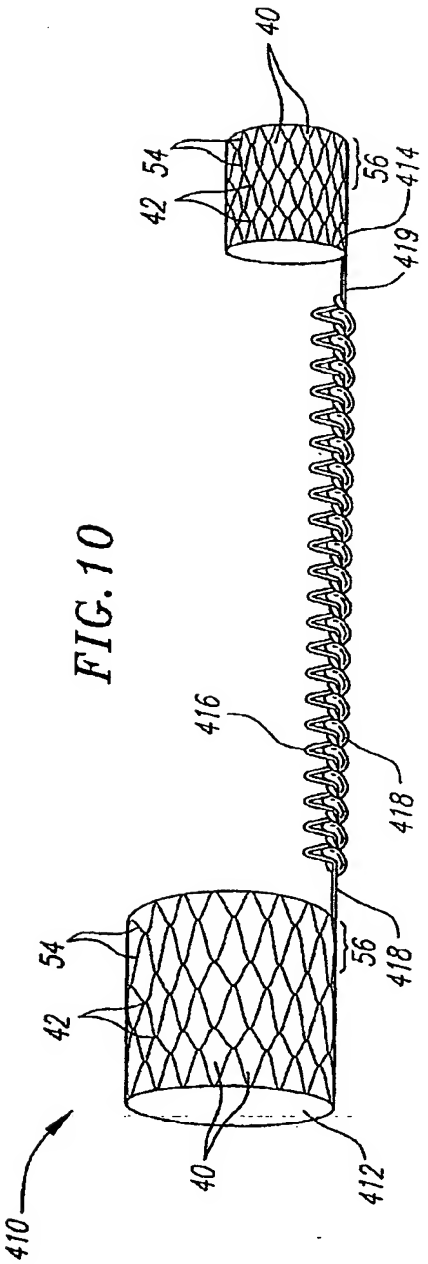

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FIG. 10

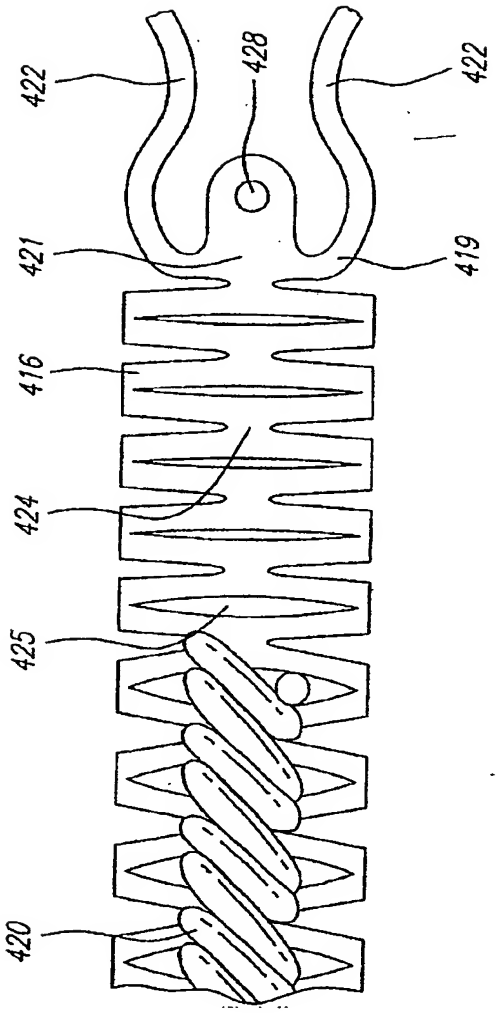
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FIG. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2005/044373

A. CLASSIFICATION OF SUBJECT MATTER
A61F2/24 A61B5/107

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/204138 A1 (CHOI STEVEN B) 30 October 2003 (2003-10-30) paragraph [0001] - paragraph [0048]; figures 1-7	1-12
Y	WO 98/51365 A (UROCATH CORPORATION) 19 November 1998 (1998-11-19) page 1, line 4 - page 14, line 14; figures 1-3	1-12
Y	WO 03/037171 A (CARDIAC DIMENSIONS, INC; ADAMS, JOHN, M; REUTER, DAVID, G; MATHIS, MAR) 8 May 2003 (2003-05-08) paragraphs [0070], [0071]; figures 10,11	10
A	US 5 851 210 A (TOROSSIAN ET AL) 22 December 1998 (1998-12-22) the whole document	1-12

-/--

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 April 2006	19/04/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Skorovs, P

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2005/044373

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/74565 A (WILSON-COOK MEDICAL INC) 14 December 2000 (2000-12-14) the whole document	1-12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/044373

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13-19
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2005/044373

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003204138 A1	30-10-2003	US 2005119567 A1	02-06-2005
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		US 5785641 A	28-07-1998
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